Message

From: Garber, Kristina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4FBFBF6569041F4BD559765E027AA31-KRISTINA GARBER]
Sent: 12/17/2019 3:09:05 PM
To: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Connolly, Jennifer [Connolly.Jennifer@epa.gov]; Peck, Charles [Peck.Charles@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]
CC: Anderson, Brian [Anderson.Brian@epa.gov]
Subject: RE: WoE methodology for effects determinations

Here are the descriptions of the confidence calls in the neonic assessments:

The strongest evidence of risk is represented by cases where assumptions related to exposure and effects are not expected to have a major influence on risk conclusions and there are multiple lines of evidence indicating the potential for effects to honey bee colonies. A strong evidence of risk may be represented by a case where many measured residues for the crop of interest exceed both the colony level LOAEC and NOAEC for a relatively long duration (*e.g.*, several weeks); residues that are an order of magnitude above CFS endpoints (indicating that only a small fraction of the honey bee colony's nectar and pollen need to be from treated fields); and the observation that multiple locations in the residue trials and/or multiple crops within the crop group yielded residues above CFS endpoints. In addition, incident reports of bee kills may provide additional lines of evidence for a strong evidence of risk conclusion.

Moderate evidence of risk is represented by cases where some lines of evidence indicate risk concerns; however, not all lines of evidence suggest risk, or there are some uncertainties associated with the data that can influence the risk conclusion. An example of moderate evidence of risk may be a case where only a small proportion of residues (from a small proportion of sites) exceed CFS endpoints for a short period of time (*e.g.*, days). In this case, there is some uncertainty whether effects will occur because residues from some sites do not exceed CFS endpoints and because the relatively short exposure duration may not be sufficient to elicit effects (*i.e.*, in the available CFS studies, after 3 and 6 weeks of constant exposure, effects were observed to colonies).

The weakest evidence of risk is represented by cases where there is evidence to suggest colony level effects; however, it is not well supported by measured residue data for the chemical of interest. For example, this may be the case when only a few residues are above the CFS NOAEC but not the LOAEC and those residues only exceed for a few days and sites. Another example may be when risk findings rely exclusively on residue data that are extrapolated (bridged) from other neonicotinoids or different crop groups where the influence of crop on the magnitude of the residue is highly uncertain (*e.g.,* bridging residue data derived from seed treatment applications to turmeric seed piece treatments).

We also used Lines of Evidence tables to standardize the conclusions:

Table 5-16. Lines of evidence considered in risk call for foliar applications of thiamethoxam to cotton.

Line of evidence		**Thiamethoxam (Strong evidence of risk)**			
Chemical specific residue data		Cotton			
Residue data for other chemicals		Clothianidin, Dinotefuran, and imidacloprid			
Percent of clothianidin present in residues from thiamethoxam studies		Median: 3%; Mean: 4%; Range: 1-23%			
Measured data:	**Exceedance Attribute**	**Clothi NOAEC (19 ug ce/g)**	**Clothi LOAEC (35.5 ug ce/g)**	**Thia NOAEC (44 ug ce/g)**	**Thia LOAEC (81 ug ce/g)**
	Frequency: Number daily mean residue values > NOAEC or LOAEC	19 (FN) 47 (XFN)	9 (FN) 40 (XFN)	6 (FN) 38 (XFN)	3 (FN) 29 (XFN)
	Duration: Max Interval (d) since application with NOAEC/LOAEC exceedance	14 (FN) 28 (XFN)	9 (FN) 25 (XFN)	7 (FN) 25 (XFN)	6 (FN) 21 (XFN)
	Magnitude: Ratio of Max to NOAEC or LOAEC*	5.0x (20%) (FN)	2.7x (37%) (FN)	2.1x (48%) (FN)	1.2x (83%) (FN)

Line of evidence		Thiamethoxam (Strong evidence of risk)			
	(% of diet required to reach NOAEC or LOAEC)	218x (0.46%) (XFN)	117x (0.9%) (XFN)	82x (1.1%) (XFN)	51x (2.0%) (XFN)
Modeled Data: (90th percentile)	**Duration:** Number of days > NOAEC & LOAEC	10 (FN) 30 (XFN)	8 (FN) 24 (XFN)	7 (FN) 23 (XFN)	6 (FN) 18 (XFN)
	Magnitude: Ratio to Max to NOAEC & LOAEC* (% of diet required to reach NOAEC & LOAEC)	20.4x (4.9%) (FN) 369x (0.3%) (XFN)	10.9x (9.2%) (FN) 198 (0.5%) (XFN)	8.8x (11.4%) (FN) 159x (0.6%)(XFN)	4.8x (20.9%) (FN) 87x (1.2%) (XFN)
Modeled Data: (70th percentile)	**Duration:** Number of days > NOAEC & LOAEC	7 (FN) 22 (XFN)	4 (FN) 18 (XFN)	2 (FN) 16 (XFN)	0 (FN) 13 (XFN)
	Magnitude: Ratio to Max to NOAEC & LOAEC* (% of diet required to reach NOAEC & LOAEC)	3.2X (31%) (FN) 55X (1.8%) (XFN)	1.7X (58%) (FN) 30X (3.4%) (XFN)	1.4X (72%) (FN) 24X (4.2%) (XFN)	0.8X (NC) (FN) 13x (7.7%) (XFN)
Modeled Data: (50th percentile)	**Duration:** Number of days > NOAEC & LOAEC	3 (FN) 18 (XFN)	0 (FN) 14 (XFN)	0 (FN) 13 (XFN)	0 (FN) 10 (XFN)
	Magnitude: Ratio to Max to NOAEC & LOAEC* (% of diet required to reach NOAEC & LOAEC)	1.5x (NC) (FN) 22x (4.5%) (XFN)	<1x (NC) (FN) 12x (8.5%) (XFN)	<1x (NC) (FN) 9.5x (11%) (XFN)	<1x (NC) (FN) 5.21x (19%) (XFN)
Tier III data		None			
Crop Attractiveness & Bloom Duration**		Attractive (floral nectar); Potentially attractive (extrafloral nectar); Not attractive (pollen); Long bloom duration (indeterminant bloom)			
Managed pollinators**		Not Required, but cotton used for honey production by some commercial beekeepers			
Ecological incidents		None			
Spatial extent of risk (annual acres treated)		766,000 (average) 1,150,000 (maximum)			
Other Considerations		The extent to which bees collect nectar from extrafloral nectaries is unknown. Residue data are bridged from all 4 neonicotinoids. Note that none of the thia data exceed thia endpoints for FN.			

FN = floral nectar, XFN = extrafloral nectar, N.C. = not calculated because > 100% of the treated diet would be needed to reach the NOAEC

*Maximum measured value represents 1 day after application for floral nectar and 6 days for extrafloral nectar. Maximum modeled value represents 1 day after application for both floral and extrafloral nectar.**Based on USDA 2017